Remarks

Response to Restriction Requirement

Claims 1-10 and 30-33 have been cancelled without prejudice in response to the restriction requirement.

Rejections under 37 C.F.R. 112

Claims 11, 12, 14, and 27-28 were rejected under 35 U.S.C. 112 as indefinite. This rejection is respectfully traversed if applied to the amended claims.

Claim 11 now clearly recites that it is a population of nanoparticles wherein at least 95% of all of the nanoparticles have a diameter of less than one micron.

Claim 12 has been amended to delete the reference to small molecule and instead defines water insoluble drugs as originally defined by claim 13.

Claim 14 is cancelled since the scope is essentially the same as claim 13.

Claims 27 and 28 have been clarified as to the percentage being that of the nanoparticles. See, for example, example 5 on page 37 and example 8, on page 40.

Rejections under 35 U.S.C. 102

Claims 22-29 were rejected under 35 U.S.C. 102(b) as anticipated by Gittins, et al., Chem.Phys. Chem. 1, 110-113 (202). Claims 11-15, 17, 18, and 21-29 were rejected under 35 U.S.C. 102(b) as disclosed by Sharma, et al., Oncology Res. 8, 281-286 (1996). These rejections are respectfully traversed if applied to the amended claims.

Amendments to the Claims

Claim 11 has been amended to define the nanoparticles as non-polymeric encapsulated nanoparticles. The disadvantages associated with polymer encapsulation are discussed on pages 4-5 of the application. Nanoparticles consisting essentially of

drug, see page 7, line 12; "Nanoparticles may be used alone, or may be coated with one or more ...." page 8, lines 23-25. The embodiments wherein the drug is encapsulated by polymer are disclaimed.

Claim 22 has been amended to clearly define the nanoparticles as formed of taxane, where the formulation when administered orally has at least 5% of the bioavailability of the same taxane when administered intravenously.

Gittins

Gittins discloses a metal nanoparticle; not a nanoparticle formed of a taxane.

Sharma, et al.

Sharma, et al., describes polyvinylpyrrolidone nanoparticles of taxol. Sharma does not describe non-polymer encapsulated nanoparticles.

Sharma in fact teaches away from nanoparticles which are not polymer encapsulated, based on what is indicated to be substantially better and unexpected results obtained following injection of the polymer encapsulated nanoparticles (col. 1, page 285). Sharma does not disclose oral administration.

Rejections under 35 U.S.C. 103

Claims 16, 19, and 20 were rejected under 35 U.S.C. 103 as obvious over Sharma, et al., in combination with U.S. Patent No. 6,197,346 to Santos, et al. This rejection is respectfully traversed if applied to the amended claims.

Sharma

Sharma is discussed above. Sharma teaches away from a non-polymer encapsulated nanoparticle formulation, and does not disclose any formulation suitable for oral administration.

Santos

Santos does not make up for this deficiency. Santos describes bioadhesive formulations, all of which utilize polymer as the bioadhesive.

None of the prior art, alone or in combination, lead one to nanoparticles which are not polymer encapsulated. The claimed nanoparticles avoid the problems of polymer encapsulated nanoparticles, discussed at the bottom of page 4 to top of page 5. Even more surprisingly, these "naked" nanoparticles were orally bioavailable and effective when administered orally (see example 19, pages 47-48), for a drug, paclitaxel, that is not considered to be orally available in any form that is effective.

Allowance of claims 11-13, and 15-29, as amended, is earnestly solicited.

Respectfully submitted,

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